IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8438

Bartle, C.J. March 24, 2010

Donna R. Christensen ("Ms. Christensen" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[3] See Settlement Agreement §§ IV.B.1.a. & I.22.

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2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

In November, 2004, claimant submitted a completed supplemental Part II of the Green Form to the Trust signed by her attesting physician, John K. Frischknecht, M.D.[4] Based on an echocardiogram performed on October 6, 1999, Dr. Frischknecht attested in Part II of Ms. Christensen's Green Form that she suffered from mild mitral regurgitation and underwent surgery to repair or replace the mitral valve prior to the use of Pondimin® and/or Redux™ and surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix B-1,[6] Level III benefits in the amount of $157,546.[7]

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4. In July, 2001, claimant submitted a completed Part II of the Green Form to the Trust signed by her attesting physician, Konstantyn Szwajkun, M.D. The Trust, however, based its determinations on claimant's November, 2004 Green Form.

5. Dr. Frischknecht also attested that claimant suffered from an abnormal left atrial dimension, arrhythmias, a reduced ejection fraction in the range of 50% to 60%, New York Heart Association Functional Class III Symptoms, and irreversible pulmonary hypertension secondary to VHD. These conditions, however, are not at issue in this claim.

6. In Part I of her Green Form, Ms. Christensen requested Matrix A-1 benefits. After reviewing claimant's Green Form, the Trust determined, and claimant does not dispute, that Ms. Christensen alleged conditions consistent only with a claim for Matrix B-1 benefits, including mild mitral regurgitation and mitral valve surgery prior to use of Diet Drugs.

7. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits if he or she had "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Christensen underwent surgery to repair or replace the mitral valve following

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In the report of claimant's echocardiogram, the reviewing cardiologist, Charles F. Dahl, M.D., concluded that claimant had "trace mitral regurgitation of the prosthetic mitral valve." Under the Settlement Agreement, mild mitral regurgitation is defined as: "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

In August, 2005, the Trust forwarded the claim for review by Ionannis P. Panidis, M.D., F.A.C.C., one of its auditing cardiologists.[8] In audit, Dr. Panidis concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had mild mitral regurgitation. Dr. Panidis noted that, upon review of claimant's echocardiogram, "[t]here was only trivial (trace) mitral regurgitation within the boundaries of the tissue prosthetic mitral valve."[9]

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7. (...continued)
the use of Pondimin® and/or Redux™, the only issue is whether claimant is eligible for benefits.

8. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that Ms. Christensen was eligible to receive Level III Matrix Benefits, pursuant to the PPP, the Trust audited Ms. Christensen's claim.

9. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue, trace or trivial (physiologic) mitral regurgitation refers to a "[n]on-sustained
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Based on the auditing cardiologist's finding of trivial mitral regurgitation, the Trust issued a post-audit determination denying Ms. Christensen's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[10] In contest, claimant argued that she should prevail because: (1) her second mitral valve surgery was due to her ingestion of Diet Drugs; (2) an "echo alone, in a mitral valve replacement, is insufficient to establish the damage caused by the drugs;" (3) claimant's treating cardiologist opined, in a supplemental opinion, that claimant had moderate mitral regurgitation prior to her surgery[11]; (4) claimant has significant pulmonary hypertension, at least in part, as a result of her ingestion of Diet Drugs;

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9. (...continued)
jet immediately (within 1cm) behind the annular plane or <+ 5% RJA/LAA."

10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Christensen's claim.

11. In a letter dated March 26, 2004, Dr. Frischknecht stated that claimant suffered from moderate mitral regurgitation prior to her ingestion of Pondimin® or Redux™. The issue, however, is whether claimant had at least mild mitral regurgitation subsequent to her commencement of Diet Drug use and prior to the mitral valve surgery that is the basis of her claim. Accordingly, this finding does not establish claimant's eligibility because it addressed only the level of her mitral regurgitation prior to the commencement of her ingestion of Diet Drugs.

(5) claimant is unable to undergo an additional mitral valve replacement procedure, and her life expectancy has been diminished, as a result of her use of Diet Drugs; and (6) claimant has submitted three echocardiograms and corresponding reports as to her level of mitral regurgitation.[12]

The Trust then issued a final post-audit determination again denying Ms. Christensen's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Christensen's claim should be paid. On June 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6372 (June 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant did not submit a response to the Trust's statement of the case and thus relied only on the materials submitted during the contest phase of the audit process. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

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12. Claimant also submits that the auditing cardiologist does not indicate that he reviewed any tapes or reports submitted in support of her claim other than the October 6, 1999 echocardiogram and report.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Christensen had mild mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

After reviewing the entire Show Cause Record, we find that claimant is not eligible to receive Level III Matrix Benefits. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits for "[s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a). Under this definition, claimant, if she were found to be eligible, would have met the requirements of a Level III claim as the Trust does not contest that she had surgery to replace her mitral valve following the use of Pondimin® and/or Redux™.

Claimant, however, must also establish her eligibility for benefits. In PTO No. 3192 (Jan. 7, 2004), we noted that simply meeting the definition of Matrix Level III as set forth in

the Settlement Agreement is insufficient to qualify for Matrix Benefits. Rather, a claimant also must satisfy the eligibility requirements set forth in Section IV.B.1.a. of the Settlement Agreement. As we stated, "[e]xperiencing left sided valvular heart disease is of no moment unless the claimant also passes muster under § IV.B.1.a." PTO No. 3192 at 3.

The Settlement Agreement states that the following Class Members are eligible to receive Matrix Compensation Benefits:

> Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement defines FDA Positive, in pertinent part, as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, to be eligible to seek Level III Matrix Benefits for her mitral valve claim, Ms. Christensen must establish that she suffered from at least mild mitral regurgitation after she ingested Diet Drugs and prior to her second mitral valve surgery, which forms the basis for her claim.

Ms. Christensen has not established that there is a reasonable medical basis for her attesting physician's finding that she suffered from mild mitral regurgitation. First, and of

crucial importance, claimant does not adequately contest the diagnosis of Dr. Panidis that claimant did not have mild mitral regurgitation. Where, as here, a specific determination is made by the auditing cardiologist, a claimant cannot simply request that the court disregard the auditing cardiologist's finding. Accepting claimant's assertion would be inconsistent with this court's decision to impose a 100 percent audit requirement for all claims for Matrix Benefits. PTO No. 2662 at 13 (Nov. 16, 2002).

In addition, despite an opportunity to do so, claimant has not provided any echocardiogram or other materials permitted under the Settlement Agreement that establish she is eligible to receive Matrix Benefits. Although claimant relied on additional echocardiogram reports, such reliance is misplaced as the echocardiograms performed prior to claimant's second mitral valve surgery (October 15, 1999) did not conclude that she had at least mild mitral regurgitation.[13] Specifically, in the report of claimant's January 19, 1998 echocardiogram, Dr. Dahl concluded that "[t]here was no mitral regurgitation." In addition, in the report of claimant's October 6, 1999 echocardiogram, Dr. Dahl

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13. Claimant also submitted the reports relating to echocardiograms performed after her second mitral valve surgery, which forms the basis of her claim. As these echocardiograms do not demonstrate that Ms. Christensen suffered from at least mild mitral regurgitation after she ingested Diet Drugs and prior to October 15, 1999 (the date of her second mitral valve surgery, which forms the basis of her claim), they cannot render Ms. Christensen eligible to receive Matrix Benefits.

found only "trace mitral regurgitation of the prosthetic mitral valve."

Finally, claimant's assertion that she is entitled to Matrix Benefits because her second mitral valve surgery, pulmonary hypertension, and reduced life expectancy are due to her ingestion of Diet Drugs also is erroneous. Causation is not at issue in resolving Ms. Christensen's claim for Matrix Benefits. Rather, claimant must show that she meets the objective requirements set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred ....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. To be eligible to receive Matrix Benefits for mitral valve claims, the Settlement Agreement clearly and unequivocally requires a claimant to prove that he or she suffered from at least mild mitral regurgitation after the ingestion of Diet Drugs and before the condition that forms the basis for the claim. We must apply the Settlement Agreement as written. Accordingly,

claimant's assertion as to the cause of the mitral valve surgery that is the basis of her claim is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had mild mitral regurgitation after she ingested Diet Drugs and prior to her second mitral valve surgery that forms the basis for her claim. Therefore, we will affirm the Trust's denial of Ms. Christensen's claim for Matrix Benefits.